



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

February 03, 2015

Hitachi Aloka Medical, Ltd.  
% Angela Van Arsdale  
Regulatory Affairs/Quality Assurance Manager  
10 Fairfield Blvd.  
WALLINGFORD CT 06492-7502

Re: K140639

Trade/Device Name: Prosound F75 Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: March 11, 2014  
Received: March 12, 2014

Dear Ms. Van Arsdale:

This letter corrects our substantially equivalent letter of April 16, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Prosound F75 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>ASU-1010</u>	<u>ASU-1012</u>	<u>ASU-1013</u>	<u>ASU-1014</u>	<u>UST-567</u>	<u>UST-675P</u>
<u>UST-677P</u>	<u>UST-678</u>	<u>UST-2265-2</u>	<u>UST-2266-5</u>	<u>UST-5293-5</u>	<u>UST-5296</u>
<u>UST-5411</u>	<u>UST-5415</u>	<u>UST-5417</u>	<u>UST-5418</u>	<u>UST-5419</u>	<u>UST-5713T</u>
<u>UST-9115-5</u>	<u>UST-9118</u>	<u>UST-9120</u>	<u>UST-9130</u>	<u>UST-9132I</u>	<u>UST-9132T</u>
<u>UST-9133</u>	<u>UST-9135P</u>	<u>UST-9146I</u>	<u>UST-9146T</u>	<u>UST-9147</u>	<u>UST-52105</u>
<u>UST-52110S</u>	<u>UST-52114P</u>	<u>UST-52119S</u>	<u>UST-52120S</u>	<u>UST-52121S</u>	<u>UST-52124</u>
<u>UST-52126</u>	<u>UST-52127</u>	<u>UST-52128</u>	<u>BF UC180F</u>	<u>GF UCT180F</u>	<u>GF UC140P-AL5</u>
<u>GF UCT140-AL5</u>		<u>GF UE160-AL5</u>		<u>TGF UC180J</u>	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Jeffrey J.  
Ballyns -S

Digitally signed by Jeffrey J. Ballyns -S  
DN: c=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People,  
0.9.2342.19200300.100.1.1=2000569725,  
cn=Jeffrey J. Ballyns -S  
Date: 2015.03.03 14:51:22 -05'00'

for

Robert Ochs  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K140639

Device Name

Prosound F75

Indications for Use (Describe)

The Hitachi Aloka Medical, Ltd. Prosound F75 is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal; Abdominal; Intra-operative; Intra-operative (neurosurgery); Laparoscopic; Pediatric; Small Organ; Neonatal Cephalic; Trans-rectal; Trans-vaginal; TEE (non-cardiac); Musculo-skeletal; Cardiac Adult; Cardiac Adult - TEE; Cardiac Neonatal; Cardiac Pediatric; Cardiac Pediatric - TEE; Peripheral Vascular; and Gynecological applications.

The device is not indicated for Ophthalmic applications.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Hitachi Prosound F75

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Note 1	
	Abdominal	P	P	P		P	Note 1	
	Intra-operative (Specify)*	P	P	P		P	Note 1	
	Intra-operative (Neurosurgery)	P	P	P		P	Note 1	
	Laparoscopic**	N	N	N		N	Note 1	
	Pediatric	P	P	P		P	Note 1	
	Small Organ (Specify)*	P	P	P	P	P	Note 1	
	Neonatal Cephalic	P	P	P		P	Note 1	
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	
	Trans-vaginal	P	P	P		P	Note 1	
	TEE (non-cardiac)	P	P	P		P	Note 1	
	Trans-esoph. (non-Card.)	P	P	P		P	Note 1	
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	
	Musculo-skel. (Superfic.)							
	Other: (Specify) *	P	P	P		P	Note 1	
	Other: Gynecological	P	P	P		P	Note 1	
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1, 2	
	Cardiac Adult, TEE	P	P	P	P	P	Note 1, 2	
	Cardiac - Neonatal	P	P	P	P	P	Note 1, 2	
	Cardiac - Pediatric	P	P	P	P	P	Note 1, 2	
	Cardiac - Pediatric, TEE	P	P	P	P	P	Note 1, 2	
Peripheral Vessel	Peripheral Vascular	P	P	P	P	P	Note 1, 2	
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD/ PWD **Note 2:** B/CWD, B/CD/CWD

\*: Specification for "Other" Airways, Tracheobronchial tree, Gastrointestinal Tract and Surrounding Organs

Applications: Small Organ-(breast, testes, &amp; thyroid..), Intra-operative – (liver, pancreas, gall bladder...)

\*\* Laparoscopic indication for use cleared via K110673

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)*Prescription Use Only (Per 21 CFR 801.109)*

(Division Sign-Off)

Division of Radiological Health

Office of *In Vitro* Diagnostics and Radiological Health

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-567

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*	P	P	P		P	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular	P	P	P	P	P	Note 1	
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD/ PWD

\*Applications: Small Organ-(breast, testes, &amp; thyroid..)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-675P

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	
	Trans-vaginal	P	P	P		P	Note 1	
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD/ PWD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-677P

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-678

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD/ PWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: ASU-1010

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Note 1	
	Abdominal	P	P	P		P	Note 1	
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/PWD, B/CD, M/CD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: ASU-1012

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		N	Note 1	
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		N	Note 1	
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological	P	P	P		N	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD/ PWD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: ASU-1013

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*	P	P	P		N	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD, B/CD/ PWD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-2265-2

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult				P			
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD/ PWD **Note 2:** B/CWD, B/CD/CWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-2266-5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Other: (Specify) *							
	Other: Gynecological							
	Cardiac Adult				P			
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
Peripheral Vessel	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
	Peripheral Vascular				P			
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD/ PWD **Note 2:** B/CWD, B/CD/CWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-5293-5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1, 2	
	Cardiac Adult, TEE	P	P	P	P	P	Note 1, 2	
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD/ PWD **Note 2:** B/CWD, B/CD/CWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-5411

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*	P	P	P		P	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	Note 1	
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD/ PWD

\*Applications: Small Organ-(breast, testes, &amp; thyroid..), Intra-operative – (liver, pancreas, gall bladder...)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-5415

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*	P	P	P		P	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	Note 1	
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD/ PWD

Applications: Small Organ-(breast, testes, &amp; thyroid..), Intra-operative – (liver, pancreas, gall bladder...)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-5417

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*	P	P	P		N	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular	P	P	P		N	Note 1	
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD, B/CD/ PWD

Applications: Small Organ-(breast, testes, &amp; thyroid..), Intra-operative – (liver, pancreas, gall bladder...)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-5419

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		N	Note 1	
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular	P	P	P		N	Note 1	
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD, B/CD/ PWD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-5713T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*	P	P	P		N	Note 1	
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/CD, M/CD

Applications: Intra-operative – (liver, pancreas, gall bladder...)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-9115-5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		N	Note 1	
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological	P	P	P		N	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/CD, M/CD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-9118

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Note 1	
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note 1	
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Other: (Specify) *							
	Other: Gynecological	P	P	P		P	Note 1	
	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
Peripheral Vessel	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD, B/CD/ PWD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-9120

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*	P	P	P		N	Note 1	
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic	P	P	P		N	Note 1	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD

Applications: Intra-operative – (liver, pancreas, gall bladder...)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-9130

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Note 1	
	Abdominal	P	P	P		P	Note 1	
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/CD, M/CD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-9132 I &amp; T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*	P	P	P		N	Note 1	
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD, B/CD/ PWD

Applications: Intra-operative – (liver, pancreas, gall bladder...)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-9133

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*	P	P	P		P	Note 1	
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic	P	P	P		P	Note 1	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/PWD, M/CD,B/CD, B/CD/ PWD

Applications: Intra-operative – (liver, pancreas, gall bladder...)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-9135P

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		N	Note 1	
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** M/CD, B/CD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-9146 I &amp; T

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*	P	P	P		N	Note 1	
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/CD, M/CD

Applications: Intra-operative – (liver, pancreas, gall bladder...)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-9147

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Note 1	
	Abdominal	P	P	P		P	Note 1	
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD, B/CD/ PWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-52105

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1, 2	
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** M/CD, B/PWD, B/CD **Note 2:** B/CWD, B/CD/CWD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-52110S

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal	P	P	P	N	N	Note 1, 2	
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE	N	N	N	N	N	Note 1, 2	
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** M/CD, B/CD **Note 2:** B/CWD, B/CD/CWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-52120S

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal	P	P	P	P	P	Note 1, 2	
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE	N	N	N	N	N	Note 1, 2	
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD **Note 2:** B/CWD, B/CD/CWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-52114P

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)	P	P	P		N	Note 1	
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** M/CD, B/CD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-52119S

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE	P	P	P	P	N	Note 1, 2	
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD **Note 2:** B/CWD, B/CD/CWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-52121S

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE	P	P	P	P	P	Note 1, 2	
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD **Note 2:** B/CWD, B/CD/CWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-52124

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic	P	P	P	P	P	Note 1, 2	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal	P	P	P	P	P	Note 1, 2	
	Cardiac - Pediatric	P	P	P	P	P	Note 1, 2	
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/PWD, M/CD, B/CD, B/CD/ PWD **Note 2:** B/CWD, B/CD/CWD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: GF-UE160 AL5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	Note 1	
	Intra-operative (Specify)*	P	P	P		P	Note 1	
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)	P	P	P		P	Note 1	
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify)							
	Others (Specify) *	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: Note 1: B/M, M/CD, B/PWD, B/CD

\*: Specification for "Others" Gastrointestinal Tract and Surrounding Organs

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: GF-UCT180

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	Note 1	
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)	P	P	P		P	Note 1	
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify)							
	Others (Specify) *	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD

\*: Specification for "Others" Gastrointestinal Tract and Surrounding Organs

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: BF-UC180F

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)	P	P	P		P	Note 1	
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify)							
	Others (Specify) *	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: Note 1: B/PWD, M/CD, B/CD

\*: Specification for "Others" Airways, Tracheobronchial tree

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: TGF-UC180J

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	Note 1	
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)	P	P	P		P	Note 1	
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify)							
	Others (Specify) *	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K123828)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD

\*: Specification for "Others" Gastrointestinal Tract and Surrounding Organs

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-52126

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE	N	N	N	N	N	Note 1, 2	
	Cardiac - Neonatal							
	Cardiac - Pediatric							
Peripheral Vessel	Cardiac – Pediatric, TEE							
	Peripheral Vascular							
	Other (spec.)							

N = new indication.

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD **Note 2:** B/CWD, B/CD/CWD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-5296

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal	P	P	P	N	P	Note 1, 2	
	Cardiac - Pediatric	N	N	N	N	N	Note 1, 2	
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K122537)

Combination of each operating mode includes: **Note 1:** B/M, M/CD, B/CD, B/CD/ PWD **Note 2:** B/CWD, B/CD/CWD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-5418

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic	N	N	N		N	Note 1	
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Other: (Specify) *							
	Other: Gynecological							
	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
Peripheral Vessel	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE							
	Peripheral Vascular							
	Other (spec.)							

N = new indication.

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD., B/CD/ PWD

Applications: Intra-operative – (liver, pancreas, gall bladder...)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: GF-UC140P-AL5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)	P	P	P		P	Note 1	
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Other: (Specify) *	P	P	P		P	Note 1	
	Other: Gynecological							
	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
Peripheral Vessel	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K130058 - Olympus)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD, B/CD/ PWD

\*: Gastrointestinal Tract and Surrounding Organs

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: GF-UCT140-AL5

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)	P	P	P		P	Note 1	
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Other: (Specify) *	P	P	P		P	Note 1	
	Other: Gynecological							
	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
Peripheral Vessel	Cardiac - Pediatric							
	Cardiac – Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication. P = previously cleared by FDA (K130058 - Olympus)

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD, B/CD/ PWD

\*: Gastrointestinal Tract and Surrounding Organs

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: ASU-1014

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Note 1	
	Abdominal	N	N	N		N	Note 1	
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological	N	N	N		N	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication.

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD, B/CD/ PWD**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-52128

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify) *							
	Other: Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE	N	N	N	N	N	Note 1, 2	
	Cardiac - Neonatal							
	Cardiac - Pediatric							
Peripheral Vessel	Cardiac – Pediatric, TEE							
	Peripheral Vascular							
	Other (spec.)							

N = new indication.

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD, B/CD/ PWD **Note 2:** B/CWD, B/CD/CWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: PROSOUND F75

Transducer: UST-52127

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	TEE (non-cardiac)							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other: (Specify)							
	Other: Gynecological							
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1, 2	
	Cardiac Adult, TEE							
	Cardiac - Neonatal							
	Cardiac - Pediatric							
	Cardiac - Pediatric, TEE							
Peripheral Vessel	Peripheral Vascular							
	Other (spec.)							

N = new indication

Combination of each operating mode includes: **Note 1:** B/M, B/PWD, M/CD,, B/CD/ PWD **Note 2:** B/CWD, B/CD/CWD(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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**510(k) Summary of Safety and Effectiveness in accordance with  
21 CFR Part 807, Subpart E, Section 807.92.**

21 CFR 807.92, Subsection a

1. Submitter's Information

Hitachi Aloka Medical, Ltd.  
10 Fairfield Boulevard  
Wallingford, CT 06492-5903

Contact:  
Angela Van Arsdale  
RA/QA Manager

Telephone: (203) 269-5088 Ext: 346  
Fax Number: (203) 269-6075

Date Prepared: February 24, 2014

2. Device / Common / Classification Name / Classification / Product Code:

Device Proprietary Name – Prosound F75 Diagnostic Ultrasound System  
Common name - Diagnostic Ultrasound System and Transducers  
Classification name - System, Imaging, Pulsed Doppler, Ultrasonic  
Classification: Class II  
Product Code: 90-IYN 892.1550 Ultrasonic Pulsed Imaging System  
90-IYO 892.1560 Ultrasonic Pulsed Echo Imaging System  
90-ITX 892.1570 Diagnostic Ultrasound Transducer

3. Legally Marketed Predicate Device(s):

Hitachi Prosound F75 Diagnostic Ultrasound Scanner [K123828]

4. Device Description:

An ultrasound diagnostic system with the following features:

- Ultrasound transducer(s) – to generate the transmitted ultrasound energy and detect the reflected echoes
- Ultrasound transducer accessories (standard and optional) - to maximize functional usage of transducer(s) in various modes of operation
- A computer system - to control the transducer and analyze the signals resulting from the reflected echoes
- A video monitor with optional image recorder - to display the computed image or derived Doppler data

5. Indication for Use:

The Hitachi Aloka Medical, Ltd. Prosound F75 is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal; Abdominal; Intra-operative; Intra-operative (Neurosurgery); Pediatric; Small Organ; Neonatal Cephalic; Trans-rectal; Trans-vaginal; TEE (non-cardiac); Musculo-skeletal; Cardiac Adult; Cardiac, Adult -TEE; Cardiac - Neonatal; Cardiac - Pediatric; Cardiac - Pediatric, TEE; Peripheral Vascular; and Gynecological applications.

The device is not indicated for Ophthalmic applications.

## 6. Comparison to predicate device:

The Hitachi Aloka Medical, Ltd. Hitachi Prosound F75 Diagnostic Ultrasound device is technically comparable and substantially equivalent to the currently marketed Hitachi Prosound F75 Diagnostic Ultrasound Scanner [K123828]. The subject and predicate systems are track 3 systems that incorporate the same fundamental and scientific technologies.

	Subject	Predicate
	Hitachi Aloka Medical, Ltd. Hitachi Prosound F75 Diagnostic Ultrasound Scanner	Hitachi Aloka Medical, Ltd. Prosound F75 Diagnostic Ultrasound Scanner [K123828]
Function		
DICOM	YES	YES
DICOM SR	YES	YES
Real-time Tissue Elastography (feature updated)	YES	YES
Real-time 3D (feature updated)	YES	YES
STIC	YES	YES
3D STIC (STIC image enhancement)	YES	N/A
Automated IMT Measurement	YES	YES
Automated NT Measurement	YES	YES
eTRACKING	YES	YES
FMD	YES	YES
Wave Intensity	YES	YES
EFV	YES	YES
Stress Echo	YES	YES
AIP	YES	YES
DSD (Dynamic Slow-motion Display) [Predicate K122537]	YES	N/A
CHE	YES	N/A
Real-Time Doppler Auto Trace	YES	YES
Spatial Compound	YES	YES
FAM	YES	YES
Measurement Function	YES	YES
Dual Doppler	YES	N/A
Trapezoid	YES	YES
TDI	YES	YES
Display modes	B, 2B, 4B, M, PW,CW,B/M,B/PW,B/CW, B(F), 2B(F), 4B(F), M(F), B(T),2B(T),4B(T),M(T), B(T)/M(T),B(T)/PW(T),B(T)/C W, B/M/PW, B(F)/M(F)/PW, M/PW,M(F)/PW,M(T)/PW	B, 2B, 4B, M, PW,CW,B/M,B/PW,B/CW, B(F), 2B(F), 4B(F), M(F), B(T),2B(T),4B(T),M(T), B(T)/M(T),B(T)/PW(T),B(T)/C W, B/M/PW, B(F)/M(F)/PW, M/PW,M(F)/PW,M(T)/PW
PW Reference frequency	1.5, 1.88, 2.14, 2.50, 3.00, 3.33, 3.75, 4.28, 5.00, 6.00, 7.50, 8.00MHz	1.88, 2.14, 2.50, 3.00, 3.33, 3.75, 4.28, 5.00, 6.00, 7.50, 8.00MHz

21 CFR Part 807.92, Section b

1. Non-clinical Testing

No new hazards were identified with the addition of the added indications and software features. The subject device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform to applicable medical device safety standards.

2. Clinical testing:

None required

3. Conclusions:

The Hitachi Aloka Medical, Ltd. Prosound F75 Diagnostic Ultrasound scanner is substantially equivalent in safety and effectiveness to the predicate device;

- The subject and predicate device(s) are both indicated for diagnostic ultrasound imaging and fluid flow analysis.
- The subject and predicate device(s) have the same gray scale and Doppler capabilities.
- The subject and predicate device(s) have the same essential technology for imaging, Doppler functions, and signal processing.
- The subject and predicate device(s) have acoustic level below the Track 3 FDA limits.
- The subject and predicate device(s) are manufactured in accordance to FDA 21 CFR 820 Quality System Regulations.
- The subject and predicate device(s) are designed and manufactured to the same electrical and physical safety standards.
- The subject and predicate device(s) are manufactured with materials that have been tested in accordance to ISO 10993-1; all biocompatibility testing has been conducted in accordance to each component material characterization, type of body contact, and duration contact risk profile.
- The subject and predicate device(s) are designed to be re-usable and provide instructions for cleaning, disinfection, and sterilization in the Ultrasound system and transducer manuals.
- The additional functions consist of currently cleared functions that have been enhanced or blended together providing enhanced image quality.

**END OF SUMMARY**